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Takatoshi Miyahara

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STAAS & HALSEY LLP

SUITE 700

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EXAMINER

CROW, ROBERT THOMAS

ART UNIT

PAPER NUMBER

1634

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DELIVERY MODE

08/02/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/624,567

Applicant(s)

MIYAHARA ET AL.

Examiner

Robert T. Crow

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 May 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9, 11 and 12 is/are pending in the application.
- 4a) Of the above claim(s) 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 2/07; 7/07.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 21 May 2007 has been entered.

Status of the Claims

2. This action is in response to papers filed 21 May 2007 in which claim 1 was amended, no claims were canceled, and no new claims were added. Claim 12 was previously withdrawn. All of the amendments have been thoroughly reviewed and entered.

The previous rejections under 35 U.S.C. 112, second paragraph, are withdrawn in view of the amendments.

The previous rejections under 35 U.S.C. 102(b) and 35 U.S.C. 103(a) not reiterated below are withdrawn in view of the amendments. Applicant's arguments have been thoroughly reviewed and are addressed following the rejections necessitated by the amendments.

In view of Applicant's request on page 14 of the Remarks file 21 May 2007 that the request for a terminal disclaimer be held in abeyance, the previous rejections under the judicially created doctrine of obviousness-type double patenting over claims 1-5, 7, and 16-22 of U.S. Patent No. 6,916,614 are **maintained** for the reasons set forth in the previous Office Action.

Claims 1-9 and 11 are under prosecution.

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Information Disclosure Statement

3. The Information Disclosure Statements filed 2 February 2007 and 3 July 2007 are acknowledged.

However, document EP 0 889 981 A1 is not being considered because it does not correspond to U.S. Patent No. 6,128,800. In addition, European Office Action dated 2 November 2000 and the European Official Communication issued 11 May 2007 have been considered but has been lined through because there are no publication dates. See 37 CFR 1.98.

4. It is noted that Applicant has provided a copy of EP 0 882 981 A1, which does in fact correspond to U.S. Patent No. 6,128,800. This document has been considered, and is listed on the Notice of References Cited (form PTO-892) provided with this Office Action so that the correct document number is on file. Applicant does not need to file a new Information Disclosure Statement, and no copy of the document is provided because the copy of EP 0 882 981 A1 provided by Applicant is already on file with the instant application.

Claim Rejections - 35 USC § 112

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 2-3 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 2-3 are each indefinite in the recitation "said upper cover" in line 2 of each of the claims. The limitation "said upper cover" lacks antecedent basis in "a cover" as recited in line 5 of claim 1. It is suggested the word "upper" be deleted from the claims.

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Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 1, 3-6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Caillat et al (European Patent Application Publication No. EP 0 882 981 A1, published 12 September 1998) or alternatively over Caillat et al (U.S. Patent No. 3,126,800, filed 2 June 1998), each in view of Landegren et al (U.S. Patent No 4,988,617, issued 29 January 1991). Citations of Caillat et al are from U.S. Patent 3,126,800, which is an English language equivalent of the European Patent Application.

Regarding claim 1, Caillat et al teach a detection chip. In a single exemplary embodiment, Caillat et al teach Figure 5, which shows a body having a depression; namely, a cuvette 252, which is a depression, formed as a depression within the body comprised of first and second substrates 254 and 256, which are attached together to form a single body (column 5). Cover 268 rests above the body (Figure 5) to form the cuvette, which is the instantly claimed internal enclosed space. The cuvette encloses a biological sensor having DNA probes for binding to DNA (column 1, lines 17-20). The teaching of DNA encompasses gene samples.

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The internal space further comprises a plurality of measuring electrodes in the form of analysis electrodes 212 fixed within the cuvette (column 6, lines 1-10), as well as common electrode in the form of counter electrode 215 (Figure 6 and column 5, line 63-column 6, line 25). The electrodes are formed at the bottom of the space. Caillat et al also teach measurement current is selectively measured between a given analysis electrode and the counter electrode (column 6, lines 15-21), which is interpreted as measuring an electric current variation. Caillat et al further teach the measuring electrodes 212 are lined with probes (column 5, lines 40-45) so that the probes are immobilized (i.e., grafted) onto the measuring electrodes (column 1, lines 50-64). The probes are DNA probes, which are oligonucleotides (column 1, lines 20-25); thus, hybridization assays measured by the device. Common electrode 215 is part of the chip (Figure 6), which is in the enclosed space (Figure 5). Caillat et al teach also teach application of a voltage between the common electrode and the measuring electrodes to detect current variations (column 6, lines 18-20).

It is noted that the courts have held that "while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function." *In re Schreiber*, 128 F.3d 1473, 1477-78, 44 USPQ2d 1429, 1431-32 (Fed. Cir. 1997). In addition, "[A]pparatus claims cover what a device *is*, not what a device *does*." *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (emphasis in original). Therefore, the various uses recited in claim 1 (e.g., receiving gene samples) fail to define additional structural elements to the device of claim 1. Because the prior art teaches the structural elements of claim 1, the claim is obvious over the prior art.

Caillat et al do not teach the immobilized oligonucleotides are for detecting point mutations.

However, Landegren et al teach an array of immobilized oligonucleotides wherein the array comprises probes for samples of genes (Example 5 and Figure 10B) used for detecting point mutations (column 4, lines 10-20). Landegren et al further teach about 85% of mutations in the human genome are point mutations, and that detection of mutations allows prediction of a substantial number of disease traits (column 1, lines 10-40). Thus, detecting point mutations has the added advantage of allowing

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prediction of a substantial number of human disease traits by targeting the most likely form of mutation found in the human genome.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Caillat et al with the oligonucleotides for detecting point mutations as taught by Landegren et al with a reasonable expectation of success. The teachings of Landegren et al are evidence that oligonucleotides for detecting point mutations were known in the prior art at the time the claimed invention was made. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a chip having the added advantage of allowing prediction of a substantial number of human disease traits by targeting the most likely form of mutation found in the human genome as explicitly taught by Landegren et al (column 1, lines 10-40).

Regarding claim 3, the chip of claim 1 is discussed above. Caillat et al further teach the upper cover is transparent; namely, the cover is glass and allows light to pass through (column 5, lines 50-60).

Regarding claim 4, the chip of claim 1 is discussed above. Caillat et al further teach the measuring electrodes form an array; namely, Figure 6 shows measuring electrodes 212 in an array.

Regarding claim 5, the chip of claim 1 is discussed above. Caillat et al further teach the common electrode is arranged so as not to contact the measuring electrodes because Figure 6 shows counter electrode 215, which is the common electrode, does not contact measuring electrodes 212.

Regarding claim 6 the chip of claim 1 is discussed above. Caillat et al further teach different electrodes of the chip are covered with different reactants (column 2, lines 3-20), wherein the reactants are probe molecules that are DNA probes (column 1, lines 20-25), which are oligonucleotides.

Regarding claim 9, the chip of claim 1 is discussed above. A review of the specification yields no limiting definition of a "card." The online dictionary of Merriam-Webster at m-w.com defines a card as "a flat stiff usually small and rectangular piece of material (as paper, cardboard, or plastic) usually bearing information. Caillat et al teach the chip is flat (Figure 5) and is made of a glass fiber/epoxy resin

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composite material (column 5, lines 10-15), which is interpreted as 'stiff.' Thus, Caillat et al teach the chip is a "card," and the claim has been given the broadest reasonable interpretation consistent with the teachings of the specification regarding a "card" (*In re Hyatt*, 211 F.3d1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000) (see MPEP 2111 [R-1])).

10. Claims 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Caillat et al (European Patent Application Publication No. EP 0 882 981 A1, published 12 September 1998) or alternatively over Caillat et al (U.S. Patent No. 3,126,800, filed 2 June 1998, wherein the U.S. Patent is an English language equivalent of the European Patent Application), each in view of Landegren et al (U.S. Patent No 4,988,617, issued 29 January 1991)) as applied to claim 1 above, and further in view of Wilding et al (U.S. Patent No. 5,587,128, issued 24 December 1996).

Regarding claim 2, the chip of claim 1 is discussed above in Section 9.

Neither Caillat et al nor Landegren et al teach injection holes extending through the body and the cover into said depression.

However, Wilding et al teach a device for detecting polynucleotides by measuring conductivity (column 21, lines 15-20). The device of Wilding et al comprises a body having a depression (Figure 2B), an upper cover to be fixed to said body from above said depression (Figure 2B), an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B). Wilding et al also teach Figure 1C, which shows injection holes 16 extending through cover 12 and into the channel 22, which is a depression in the body of the device (column 16, lines 25-46). Wilding et al also teach the added advantage that the ports allow addition of the sample and reagents and the withdrawal of products (column 16, lines 25-46) while maintaining a seal over the device (column 4, lines 16-24).

While Wilding et al do not specifically teach the injection holes on two opposing surface of each of said body and said upper cover, the courts have held that the rearrangement of parts within a device is

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obvious when the arrangement does not specifically modify the operation of the device (*In re Japikse*, 181 F.2d 1019, 86 USPQ 70 (CCPA 1950)). See MPEP §2144.04.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Caillat et al in view of Landegren et al with the injection holes extending through the body and the cover as taught by Wilding et al with a reasonable expectation of success. The teachings of Wilding et al are evidence that injection holes extending through the body and the cover was known in the prior art at the time the claimed invention was made. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a chip having the added advantage of allowing addition of the sample and reagents and the withdrawal of products while maintaining a seal over the device as explicitly taught by Wilding et al (column 16, lines 25-46 and column 4, lines 16-24).

Regarding claim 11, the chip of claim 1 is discussed above. While Caillat et al teach heating elements in the form of resistance heater 265 (Figure 5 and column 6, lines 40-50), neither Caillat et al nor Landegren et al teach Peltier elements.

However, Wilding et al teach a device for detecting polynucleotides by measuring conductivity (column 21, lines 15-20). The device of Wilding et al comprises a body having a depression (Figure 2B), an upper cover to be fixed to said body from above said depression (Figure 2B), an enclosed internal space part, formed by said depression in said body as a result of said upper cover being fixed to said body (e.g., the device is sealed by the cover; column 4, lines 15-20 and Figure 2B). Wilding et al also teach the device has Peltier heating elements which provide the added advantage of providing both heating and cooling functions (column 17, lines 15-17).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Caillat et al in view of Landegren et al with the Peltier devices as taught by Wilding et al with a reasonable expectation of success. The teachings of Wilding et al are evidence that Peltier devices were known in the prior art at the time the claimed

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invention was made. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a chip having the added advantage of providing both heating and cooling functions as explicitly taught by Wilding et al (column 17, lines 15-17).

11. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over by Caillat et al (European Patent Application Publication No. EP 0 882 981 A1, published 12 September 1998) or alternatively over Caillat et al (U.S. Patent No. 3,126,800, filed 2 June 1998, wherein the U.S. Patent is an English language equivalent of the European Patent Application), each in view of Landegren et al (U.S. Patent No. 4,988,617, issued 29 January 1991)) as applied to claim 1 above, and further in view of Heller et al (U.S. Patent No. 5,632,957, issued 27 May 1997).

Regarding claim 7, the chip of claim 1 is discussed above in Section 9.

Neither Caillat et al nor Landegren et al teach one to one wiring.

However, Heller et al teach a the chip comprising different nucleic acids attached at each of a plurality of microlocations (column 4, lines 55-60), wherein each of the plurality of microlocations has an electrode (column 8, lines 1-17), which are measuring electrodes. Heller et al further teach each of the measuring electrodes is connected with each of a plurality of wirings on a one to one basis (Figure 3 and column 9, lines 52-64). The wiring arrangement creates an active programmable electronic matrix (column 9, lines 52-64), which has the added advantage of allowing multiplexed multistep combinatorial synthesis of nucleic acid biopolymers at each measuring electrode independently and simultaneously (Abstract). Independent simultaneous multiplexed multistep combinatorial synthesis of nucleic acid biopolymers results in rapid parallel synthesis of the immobilized oligonucleotides at the electrodes.

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Caillat et al in view of Landegren et al with the one to one wiring as taught by Heller et al with a reasonable expectation of success. The teachings of Heller et al are evidence that one to one wiring was known in the prior art at the time the claimed

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invention was made. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a chip having the added advantage of allowing rapid parallel synthesis of the immobilized oligonucleotides at the electrodes as a result of allowing multiplexed multistep combinatorial synthesis of nucleic acid biopolymers at each measuring electrode independently and simultaneously as explicitly taught by Heller et al (Abstract).

12. Claim 8-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over by Caillat et al (European Patent Application Publication No. EP 0 882 981 A1, published 12 September 1998) or alternatively over Caillat et al (U.S. Patent No. 3,126,800, filed 2 June 1998, wherein the U.S. Patent is an English language equivalent of the European Patent Application), each in view of Landegren et al (U.S. Patent No 4,988,617, issued 29 January 1991)) as applied to claim 1 above, and further in view of Wohlstadter et al (PCT International Application Publication No. WO 98/12539, published 26 March 1998).

It is noted that while claim 9 has been broadly rejected under 35 USC 103(a) as described above in Section 9, the claim is also obvious using the more narrow interpretation outlined below.

Regarding claims 8-9, the chip of claim 1 is discussed above.

Neither Caillat et al nor Landegren et al teach a measuring apparatus to which the chip becomes electrically connected and which measures current (i.e., claim 8), or that the chip is configured to be inserted into and removed from said apparatus; i.e., an insertable cassette (i.e., claims 8 and 9).

However, Wohlstadter et al teach a chip comprising measuring electrodes and counter electrodes in the form of a cassette (page 7, lines 8-24), wherein the cassette is configured to be inserted into and removed from an apparatus comprising means for conducting electrochemiluminescence (i.e., ECL) reactions (page 84, lines 20-35). The apparatus controls electrode addressing and signal acquisition and processing (page 84, line 8-page 85, line 3), and is thus electrically connected and detects electric current (page 86, lines 8-15). Wohlstadter et al further teach the insertable cassette and apparatus have the added

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advantage of allowing execution of assays in a disposable format, thereby allowing disposable assays to be produced at a lower cost (page 113, lines 25-30).

It would therefore have been obvious to a person of ordinary skill in the art at the time the claimed invention was made to have modified the chip of Caillat et al in view of Landegren et al with the teachings of as taught by Wohlstadter et al with a reasonable expectation of success. The modification would result in a chip which becomes electrically connected and which measures current that is configured to be inserted into and removed from an apparatus (i.e., claim 8) by modifying the chip into an insertable cassette (i.e., claim 9). The teachings of Wohlstadter et al are evidence that insertable cassettes that become electrically connected to detection apparatuses were known in the prior art at the time the claimed invention was made. The ordinary artisan would have been motivated to make such a modification because said modification would have resulted in a chip having the added advantage allowing disposable assays to be produced at a lower cost as a result of allowing as explicitly taught by Wohlstadter et al (page 113, lines 25-30).

Response to Arguments

13. Applicant's arguments filed 21 May 2007 with respect to the previous rejections of the claims have been considered but are moot in view of the new ground(s) of rejection necessitated by the amendments.

Conclusion

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert T. Crow whose telephone number is (571) 272-1113. The examiner can normally be reached on Monday through Friday from 8:00 am to 4:30 pm.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jehanne Sitton
JEHANNE SITTON
PRIMARY EXAMINER

7/27/07

Robert T. Crow
Examiner
Art Unit 1634

